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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,561	10/22/2001	Yoshio Jo	763-29	3304

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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,561

Applicant(s)

JO ET AL.

Examiner

Simon J. Oh

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34,36-55,57-60 and 62-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34,36-55,57-60 and 62-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment and response, both received on 04 August 2003. Receipt is acknowledged of the applicant's supplemental amendment, received on 22 September 2003.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 35, 56, and 61 under 35 U.S.C. 103(a) is rendered moot with the cancellation of those claims.

The rejection of Claims 34, 36-55, 57-60, and 62-66 under 35 U.S.C. 103(a) is maintained.

Claims 67-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soe *et al.* (European Patent Application No. EP 0 956 869 A2) in view of Columbo *et al.* (U.S. Patent No. 4,340,731), Edwardson *et al.*, and Sugitachi *et al.* (U.S. Patent No. 4,265,233)

The Soe II reference discloses a tissue sealant that comprises carboxymethyl cellulose, with a degree of etherification of preferably 0.5% to 1.5% and most preferably 0.6% to 0.8% (See Sections [0016] to [0017]). The sealant preferably further comprises enzymes such as thrombin, and proteins, which include fibrinogen and coagulation factor XIII. All components of

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the tissue sealant are biodegradable (See Sections [0015] and [0029]). A method of preparing the tissue sealant is disclosed (See Section [0039]).

The Soe II reference does not disclose the chemical bonding of proteins to cellulosic fibers through treatment with carbodiimide, nor does the reference disclose a process for the etherification of low-substituted cellulose fibers, nor does it teach a tissue sealant in the form of a fabric.

The Columbo *et al.* patent teaches a process for etherification of cellulose fibers into soluble carboxymethyl cellulose. The fibers are treated with a solution of sodium hydroxide and further treated with a monochloro acetic acid solution to form carboxymethyl cellulose with a degree of substitution equal to 0.8, and then dried. (See Column 6, Example 3).

The Edwardson *et al.* patent teaches a fibrin composition useful as a surgical sealant to provide hemostasis (See Abstract). The patent discloses that a thrombin-like enzyme may be immobilized on a support through various activation chemistries, including carbodiimide groups. Suitable supports for immobilization include cellulose and cellulose derivatives (See Column 8, Line 63 to Column 9, Line 35).

The Sugitachi *et al.* patent discloses materials for wound healing having Factor XIII and thrombin affixed to it (See Abstract; and Column 3, Lines 18-40). The material further comprises a structure which may take various forms, including cotton, non-woven fabrics, woven fabrics, knitted fabrics, twisted yarns, knitting yarns, bandages, and burn dressings, as well as absorbable materials. Natural polymers may be used to make up these structures, including cellulose, carboxymethyl cellulose, and methyl cellulose (See Column 1, Line 39 to Column 2, Line 4). Examples are disclosed where surgical gauze was treated and then imparted

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with Factor XIII and thrombin (See Examples 1 and 2). The material is described as being useful for protecting a wound site and promoting the formation of fibrin for long periods of time (See Column 8, Lines 55-68).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the references of the prior art into the object of the rejected claims. Edwardson *et al.* provides a motivation, disclosing that immobilization of a thrombin-like enzyme can prevent contamination of the composition (See Edwardson *et al.*, Column 8, Lines 57-62). The Soe II patent states that the use of low-substituted carboxymethylcellulose is preferred for the disclosed invention. Therefore, one of ordinary skill in the art would seek to find methods of producing a low-substituted cellulose ether in order to carry out the best mode of the invention described in the Soe II patent. The Columbo *et al.* patent discloses such methods of production. From there, further treatment of the material with carbodiimide according to Edwardson *et al.* may be carried out for the reasons described above. One of ordinary skill in the art would be motivated to combine the disclosure of Sugitachi *et al.* with that of Soe II so as to provide a suitable vehicle for substances such as Factor XIII and thrombin that is also capable of protecting a wound site. As stated in *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), "It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. As this court explained in *Crockett*, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art." In this case, both the Soe II and Sugitachi *et al.* references deal with wound-treating compositions that may comprise carboxymethyl cellulose, thrombin, and Factor XIII. With the

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combined disclosure of the prior art, it becomes obvious to one of ordinary skill in the art that carboxymethyl cellulose, as a vehicle for substances such as thrombin, fibrinogen, and Factor XIII, can take various forms, including the sealant of Soe II, the fibers of Columbo *et al.*, and the fabrics as disclosed in Sugitachi *et al.* Furthermore, it is the position of the examiner that as the instantly claimed invention has been made obvious by the prior art, the features embodied in the Claims 67-74, fibrinomer absorptivity, maximum platelet agglutination rate, agglutination percentage, adhered cell count, and mean hemostasis time, would be inherent to the disclosure of the prior art. Absent a demonstration that such features would be unexpected by one of ordinary skill in the art, the examiner does not give patentable weight to these claim limitations. Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 22 September 2003 have been fully considered but they are not persuasive.

In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the

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time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

It is unclear why the applicant argues against the prior art by pointing out the disclosure of the various references show products such as bandages, pads, and sutures and does not explicitly state fibers with a wound healing benefit when 1) these very products are presumably constructed from cellulose fibers that are etherified and/or affixed with coagulation proteins; and 2) such products are presumably used for the purpose of treating wounds. It is the position of the examiner that as the collective prior art discloses a product that reads on the limitations of the instant claims and contains the same components, it would function in the same as claimed by the applicant. The examiner shifts the burden onto the applicant to clearly distinguish between what is claimed from what is disclosed collectively in the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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